FDA Site Inspection Checklist

At least one week before the scheduled visit, the PI/designated study staff should complete the following activities:

Task	Items	Done	NA	Notes
Audit Notification				
Notify all parties of impending audit	Sponsor			
	IRB			
	Principal investigator			
	Subinvestigators			
	Pharmacy			
	Laborator(ies)			
	Office of Research			
	Medical Records			
	Administration			
	Legal counsel			
Reserve audit space	Work space			
	phone			
	copier			
	table			
Organization				
Study overview	Prepare general overview of study			
	List personnel and delegated			
Subject lists	List all subjects including name, contact info., enrollment and completion dates, and MRN#			
	List all subjects screened with enrollment or reason not enrolled			
PI Current Active Studies	List of Principal Investigator's current active studies			
File Management				
Organize files by heading and arrange in chronological (or reverse chronological) order	Protocol (all versions)			
	Investigators' Brochure (all versions)			
	Protocol amendments			
	Form FDA 1572 or Declaration of Investigator (DOI- device studies), all versions			
	CVs for PI and Sub-investigators listed on all versions of Form FDA 1572, DOI			
IRB files *Note: Pay attention to date of IRB notification and date of IRB acknowledgment and/or approval*	Approval Letter (initial) for initial protocol with original informed consent			
	Amendment approval(s) with the approved informed consent			
	Approvals for:			
	Periodic or Annual Reports			
	Renewal Documents			
	Notification of:			
	Adverse Events			
	Deaths			
	Acknowledgement of:			
	IND Safety Reports			

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At least one week before the scheduled visit, the PI/designated study staff should complete the following activities:

	Study Termination			
	Final Summary			
Task	**Items**	**Done**	**NA**	**Notes**
File Management				
Communication	Sponsor correspondence			
	CRO correspondence			
	Monitoring Log			
Laboratory	Laboratory certification(s)			
	Laboratory normal ranges			
	CV of laboratory director			
Drug accountability	Receipt of Drug			
	Dispensing			
	Return			
Adverse Events	Serious adverse event reports made to sponsor			
	Serious adverse event reports received			
Subject documents	Completed CRFs for each subject			
	Source documents/medical record for			
Device Accountability-device log to include	Receipt of Device			
	Dispensing (where applicable, includes			
	Return (where applicable)			
Data Review Complete the following review and note any issues to discuss with PI, Department, Temple officials				
Review for each subject enrolled	Review Inclusion/Exclusion Criteria			
	Document reason for excluded subjects			
	CRFs completed for each enrolled subject			
	Source documentation for all CRF entries			
	Data Clarification issues satisfied			
	Consent obtained for all subjects			
	Verify correct version of informed consent			
	Confirm 'Notes to File' present as appropriate			
Medical records and/or study files documenting data	Condition of subject at time of entry into			
	All exposure to test article			
	Concomitant medications			
	Clinical assessments of subject during			
	Laboratory reports			
	Diagnostic test reports			
	Diagnostic test films (if applicable)			
	Dose modifications			
	Adverse events			
	Protocol exceptions			
	Early withdrawals			

This document was developed by the Temple University IRB with assistance from the Clinical Resource HUB at the University of California, San Francisco.